

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MINNESOTA

1/21/03

---

IN RE ST. JUDE MEDICAL, INC., :  
SILZONE HEART VALVES PRODUCTS :  
LIABILITY LITIGATION : MDL DOCKET NO. 1396

**JOINT STATUS CONFERENCE REPORT**

**(Status Conference— January 23, 2003, 4:30 p.m.)**

The parties have met and conferred and submit this status report to the Court.

**1. DISCOVERY MATTERS**

**A. Discovery Issues Outstanding**

The parties have conferred on several discovery issues since the last status conference. The status of outstanding discovery issues includes the following:

- a. Missing animal study documents. Class counsel are concerned about their repeated discoveries of documents missing from St. Jude Medical's production, including documents pertaining to animal studies of the Silzone-coated Epic valve. A number of the missing documents had been provided to counsel in state court actions, but not to MDL counsel. The missing Epic documents in particular are impeding plaintiffs' expert, Dr. Wilson, from completing his pathology review, which is necessary for certain preemption depositions to proceed.

- b. EPIC valve animal study pathology slides. Plaintiffs had requested that these 2,200 slides be couriered to their expert, Dr. Wilson, in Toronto, as had been done previously in this case with pathology slides relating to the Masters Series animal studies. St. Jude Medical has been unwilling to release the slides for inspection outside of its Minnesota facilities because the EPIC valve is still being marketed. St. Jude Medical has offered to make these materials available for inspection at its offices in Minnesota and the Court agreed at the last Status Conference that this was an appropriate procedure. Plaintiffs are attempting to pare down the list of slides that must be reviewed, so as to enable Dr. Wilson to review a smaller number of slides, and/or duplicates of slides, possibly in Toronto.
- c. St. Jude Medical's privilege log of withheld and redacted documents. St. Jude Medical did not complete its privilege log by December 31, 2002, as represented in the last Joint Status Conference Report, and it remains incomplete. St. Jude Medical is working to complete its privilege log, and has recently produced a new version containing additional entries. Also, the Class disagrees that several categories of documents already listed on St. Jude Medical's interim privilege log are properly withheld as privileged. The parties have initiated a

meet-and-confer process about certain categories of disputed privilege log entries, while awaiting the completion of the privilege log. Counsel for St. Jude Medical has stipulated that the deposition of James Ladner, scheduled for January 23, 2003, may be reopened if documents previously withheld as privileged must be produced, provided that questioning is limited to documents to which a privileged designation has been withdrawn by stipulation or by order of this Court.

- d. The most recent AVERT freeze data was recently produced by St. Jude Medical.
- e. St. Jude Medical has produced the “non-electronic” documents from the personal files of St. Jude Medical’s medical director, Dr. Frater, which had not previously been collected from Dr. Frater’s New York office. St. Jude Medical continues to work on producing Dr. Frater’s electronic documents, as represented in the last Joint Status Report.
- f. Declassification of “Top Accounts” and AVERT documents. The parties have conferred about declassifying documents pertaining to St. Jude Medical’s “Top Accounts” survey of Silzone valve implant centers. The parties have agreed that the documents should be declassified, with codes substituted for the names of the implanting centers. Regarding data and

data analysis from the AVERT study, counsel for St. Jude Medical is working to ascertain St. Jude Medical's position on declassification of such documents.

- 
- g. St. Jude Medical personnel files. Due in part to deposition testimony about a St. Jude Medical "management by objectives" program, counsel for the Class has given counsel for St. Jude Medical a list of 36 current and former employees who, plaintiffs contend, are key St. Jude Medical personnel for whom company personnel files are sought. St. Jude Medical contends that a request to compel the production of personnel files calls for this Court to balance the plaintiffs' need for the information against the individual employees' right to privacy and that plaintiffs cannot meet their burden in this regard. The parties are conferring as to whether certain documents from a limited number of personnel files should be produced to the court for *in camera* review to determine whether these documents make any reference to Silzone.
- h. Counsel for the Class has asked St. Jude Medical's counsel for documents pertaining to complaints and Field Experience Reports (FERs) regarding Tailor and Sequin annuloplasty rings that had Silzone cuffs, which do not appear to have been produced to date. Counsel for St. Jude Medical is looking into the availability of such documents.

- i. Designation of one or more (as necessary) Custodians of Records who will verify the manner and completeness of St. Jude Medical's document production. St. Jude Medical responds that the document collection effort in this litigation has involved many lawyers and employees of the company and that no one person can be produced to testify as to its completeness. St. Jude Medical objects to a deposition as to the "manner" of the document production effort because it claims such information is attorney work product.

**B. Availability of the Court During the Deposition of James Ladner**

The deposition of St. Jude Medical in-house counsel James Ladner is scheduled for January 23, 2003, prior to the instant late-afternoon Status Conference. In the event that, during the deposition, a question is objected to based upon privilege, plaintiffs request the Court to be available by telephone to resolve the dispute so that the deposition could proceed expeditiously. St. Jude Medical disagrees that privilege objections should be adjudicated by the Court via telephonic conference during the deposition. St. Jude Medical submits that such objections should be ruled upon only after these issues are briefed and argued at a later hearing.

**C. Subpoena of Sulzer Carbomedics**

Counsel for the Class and counsel for St. Jude Medical have stipulated that documents produced pursuant to Plaintiffs' document subpoena of Sulzer Carbomedics will be deemed "CONFIDENTIAL" as defined in Pretrial Order No. 5. Counsel for the

Class have conferred with outside counsel for Sulzer Carbomedics, who reports that Sulzer's in-house counsel is preoccupied with corporate matters at present. Sulzer's outside counsel hopes to ascertain the status of Sulzer's document production soon, and further hopes to be in a position to begin producing the responsive documents by the end of January.

**D. Subpoena of Dr. Frederick Schoen**

Regarding the third-party document subpoena issued by the MDL Court to Dr. Frederick Schoen in Massachusetts, counsel for Dr. Schoen has met and conferred with Class counsel, and has agreed to produce Silzone-related documents from Dr. Schoen's files. Counsel have agreed that Dr. Schoen's objections to the subpoena are not waived by his production, and that Plaintiffs' right to compel further production, if deemed necessary, is preserved. Counsel for the Class and counsel for St. Jude Medical have stipulated that documents produced pursuant to Plaintiffs' document subpoena of Dr. Schoen will be deemed "CONFIDENTIAL" as defined in Pretrial Order No. 5.

**E. Schedule of Remaining Preemption Discovery**

The Class has completed the depositions of Alan Flory, Diane Johnson, Jonas Runquist, Donald Guzik, Tim Chase, and Maggie Walner. The depositions of James Ladner and Katherine Tweden are set for January 23 and January 31, respectively. Dates for the probable depositions of Matthew Ogle, Barbara Illingworth, J. Douglas Cameron, and Daniel Langanki are pending, although some of those depositions will depend in part on the logistics and timing of Dr. Wilson's review of pathology data, as discussed above. As previously reported, the Class intends to serve a Rule 30(b)(6) Notice of Designated Representative deposition, including the areas of inquiry previously identified to counsel

and to the Court; a Custodian of Records deposition to verify the completeness of St. Jude Medical's document production; and Requests for Admissions. Pursuant to Pretrial Order No. 22, subsequent merits discovery has been extended into May, 2003.

---

**2. REPORT ON COMMON BENEFIT FUND ACCOUNT BALANCE**

Pursuant to Pre-Trial Order #18, the escrow agent for the Plaintiffs' Litigation Expense Fund was to deliver to the Court and to Plaintiffs' counsel the first reports on sums deposited into the Fund. St. Jude Medical has not executed any settlements to date which involve MDL cases, or state cases involving parties who had agreed to participate in the Fund, so the balance of the Fund remains zero.

**3. STATUS OF RAMSEY COUNTY CASES**

A status conference with Judge Gearin in the Ramsey County cases is set for January 22, 2003 at 9:00 a.m. There are currently 20 cases pending in Ramsey County. The preemption summary judgment briefing and hearing schedule remains as reported in the last Joint Status Conference Report. The first Ramsey County trial (Nickerson v. St. Jude Medical) is set for June 23, 2003.

**4. CANADIAN LITIGATION STATUS**

In December 2002, a new Canadian class action lawsuit was filed in the province of Quebec on behalf of recipients of St. Jude Medical Silzone heart valves. With this filing, all Canadian Silzone heart valve recipients reportedly are represented in class action litigation with St. Jude Medical, as there are now actions pending in the provinces of British Columbia, Ontario, and Quebec.

**5. REPORT ON STATE AND FEDERAL COURT FILINGS**

St. Jude Medical's most recent report on state and federal court filings was forwarded to the Court by electronic mail. The totals reported are 45 federal court filings (up from 42) and 96 state court filings (up from 93).

ZIMMERMAN REED, P.L.L.P.

Dated: January 21, 2003

BY: 

Charles S. Zimmerman #120054  
J. Gordon Rudd, Jr. #222082  
David M. Cialkowski #0306526  
651 Nicollet Mall, Suite 501  
Minneapolis, MN 55402  
(612) 341-0400

**LIAISON COUNSEL FOR PLAINTIFFS**

James T. Capretz, Esquire  
Anton D. Jensen, Esquire  
CAPRETZ & ASSOCIATES  
5000 Birch Street, Suite 2500  
West Tower  
Newport Beach, CA 92660  
(949) 724-3000

Steven E. Angstreich, Esquire  
Michael Coren, Esquire  
Carolyn C. Lindheim, Esquire  
LEVY, ANGSTREICH, FINNEY,  
BALDANTE, RUBENSTEIN &  
COREN, P.C.  
Woodcrest Pavilion, Ste. 100  
Ten Melrose Place  
Cherry Hill, New Jersey 08003  
(856) 424-8967

**CO-LEAD COUNSEL FOR PLAINTIFFS**

Joe D. Jacobson, Esquire  
David T. Butsch, Esquire  
GREEN, SCHAAF & JACOBSON, P.C.  
7733 Forsyth Boulevard, Suite 700  
Clayton, Missouri 63105  
(314) 862-6800

**LEAD COUNSEL FOR CLASS II PLAINTIFFS**



HALLELAND, LEWIS, NILAN, SIPKINS &  
JOHNSON

Dated: January 21, 2003

BY:

*Tracy Van Steenburgh / Gordon Rugg*  
Tracy Van Steenburgh  
220 South Sixth St., Suite 600  
Minneapolis, MN 55402  
612-338-1838

David E. Stanley  
REED SMITH CROSBY HEAFEY  
355 South Grand Avenue, Suite 2900  
Los Angeles, CA 90071  
213-457-8000

COUNSEL FOR DEFENDANT